91-1064

NUMBER _____

IN THE

UNITED STATES SUPREME COURT

OCTOBER TERM, 1991

NICK & BARBARA LOZIER

Petitioners

vs.

F. BRANTLEY SCOTT, JR., M.D.

Respondent

PETITION FOR WRIT OF CERTIORARI FOR THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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Arnold Anderson Vickery
COUNSEL FOR PETITIONER
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QUESTIONS PRESENTED FOR REVIEW

1. Whether, as a matter of law, the District Court erred in holding that the standard for consent to a routine medical procedure or device, as developed in state common law, was the same as the standard for consent to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27.

2. Whether, as a matter of law, a human subject's consent to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, must be in writing.

3. In the alternative, whether, as a matter of law, the provisions of federal law which mandate that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, preempt state law permitting oral consent to surgery.

4A. In the alternative, whether the District Court erred in refusing to admit into evidence the provisions of federal law mandating that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-

50.27, where consent to such participation is a material issue in the lawsuit.

4B. Also in the alternative, whether the District Court erred in refusing to instruct the jury on the provisions of federal law mandating that a human subject consent in writing to participation in research involving "investigational devices," as set forth in 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27, where consent to such participation is a material issue in the lawsuit.

Certificate of Interested Persons

The undersigned counsel of record certifies that the following listed parties have an interest in the outcome of this case. These representations are made in order that the Justices of this Court may evaluate possible disqualification or recusal.

(1) Nick and Barbara Lozier, Plaintiffs/Petitioners;

(2) Arnold A. Vickery, of the firm of VICKERY, KILBRIDE, GILMORE & VICKERY, 2929 Allen Parkway, Suite 2770, Houston, Texas 77019 and Macon Cowles, Esq. of the firm, WILLIAMS, TRINE, GREENSTEIN & GRIFFITH, 1435 Arapahoe Avenue, Boulder, Colorado 80302, their attorneys.

(3) F. Brantley Scott, Jr., M.D., Defendant/Respondent;

(4) Robert Swift and Dan Brown of the firm of FULBRIGHT & JAWORSKI, 1301 McKinney Street, Houston, Texas 77010, counsel for Defendant.

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OTHER REPORTS OF OPINIONS

The only opinion that has been written in this lawsuit so far is that of the United States Court of Appeals for the Fifth Circuit. This opinion was unpublished, and Petitioners have provided a copy of the opinion in the Appendix.

GROUNDS FOR JURISDICTION OF THE UNITED STATES SUPREME COURT

The United States Court of Appeals for the Fifth Circuit delivered its opinion on July 19, 1991. The Fifth Circuit denied Petitioner's Motion for Rehearing on August 15, 1991.

This Court has jurisdiction of this Petition for Writ of Certiorari pursuant to 28 U.S.C. §1254(1).

CONSTITUTION, STATUTES AND REGULATIONS

The following Constitutional provision, statutes and regulations are involved in this case. Pursuant to Rule 14.1(f) of the Rules of the Supreme Court of the United States, Petitioners give only their citations, and set forth their text in the Appendix.

U.S. Const. art. VI, cl. 2.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360j(g) (1984).

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §360k (1984).

28 U.S.C. §1254(1)

21 C.F.R. §§ 50.1-50.27 (1980).

Medical Liability and Insurance Improvement Act of Texas, Tex.Rev.Civ.Stat.Ann. art. 4590i, §6.06.

STATEMENT OF THE CASE

A. Introduction

Nick and Barbara Lozier filed this lawsuit against Dr. F. Brantley Scott to recover personal injury damages for Dr. Scott's unauthorized insertion of an inflatable prosthesis into Nick Lozier's penis, which ultimately resulted in Mr. Lozier's total impotence. There was federal jurisdiction of their claims based on diversity of citizenship, 28 U.S.C. §1332.

The Loziers asserted three legal theories, two of which are at issue in this Petition for a Writ of Certiorari: (1) negligence based upon Dr. Scott's failure to obtain a written consent to implant the penile prosthesis from Nick Lozier, as mandated by 21 U.S.C. §360j(g) and the regulations promulgated thereunder, 21 C.F.R. §§50.20-50.27; and (2) battery. The District Court ruled against the Loziers on the negligence/informed consent theory,

first by denying their Motion for Partial Summary Judgment, and later in the context of Dr. Scott's Motion for Directed Verdict. Moreover, the District Court even refused to admit the federal regulations into evidence, except as limited impeachment of Dr. Scott, and gave the jury a limiting instruction.

The District Court allowed the Loziers to submit their battery theory to the jury, but instructed the jury that "[t]he law, however, does not require that consent to surgery be in writing." Without the benefit of the federal statute and regulations, the jury did not find that Dr. Scott had implanted the penile prosthesis without Nick Lozier's consent, and the District Court entered a take-nothing judgment against the Loziers based on the jury's verdict. The Court of Appeals for the Fifth Circuit affirmed the District Court in an unpublished opinion.

The Loziers now seek a Petition for Writ of Certiorari from this Court, pursuant to Rule 10.1(c) of the Rules of the Supreme Court of the United States. What is at stake is not only the fate of Nick and Barbara Lozier's lawsuit but also the viability of 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 as protection for those who participate in experiments involving "investigational devices," inventions for which the FDA has granted an exemption from its usual regulatory requirements so that the inventors can explore the viability of their inventions for commercial licensing and use. If this Court adopts Dr. Scott's view -- that an experimental subject's consent to the use of such a device can be oral rather than written, as the statute and regulations provide -- it will thwart Congress' intent, and could seriously undermine the public health and safety that Congress sought to protect by

prescribing extensive disclosures, to be put in writing and signed by the subject.

The Loziers maintain that the written consent requirement of the federal statute and regulations must apply in the area of experimental medical devices, both as the duty component of the Loziers' negligence/informed consent theory and as the affirmative defense to their battery theory. Believing that the Courts below have misconstrued and misapplied 21 U.S.C §360j(g), and 21 C.F.R. §50.1, et seq., and that this Petition presents an important question of federal law, the Loziers now request this Court to effect the intent of Congress and hold that this statute and these regulations do indeed mean what they say.

B. **Factual Background**

The facts germane to this Petition for Writ of Certiorari are undisputed. See Admissions of Fact

contained in the Joint Pretrial Order, included in the Appendix. As a result of an automobile accident in 1953, Nick Lozier had problems with scar tissue blocking his urethra. In 1986, he consulted Dr. Ralph Hopkins in Lander, Wyoming, about his blockage problems. Unfortunately, Dr. Hopkins removed so much of the scar tissue that Nick Lozier was rendered incontinent. Tr. at Vol. 16, p. 21. After he became incontinent, Lozier also had periodic problems with functional impotence -- not surprising for a man who constantly dripped urine, even during intercourse. Tr. at Vol. 16, p. 30. Ultimately, Dr. Hopkins referred Lozier to Dr. F. Brantley Scott in Houston, Texas for treatment of his incontinence.

Dr. Scott was a world famous urologist who achieved fame not only as a physician but also as an inventor. Dr. Scott invented two devices (and subsequent improvements on those devices) which have been used

extensively in the treatment of two major urological problems: (i) an artificial urethral sphincter used to treat **incontinence**, and (ii) an inflatable penile prosthesis used to treat **impotence**, Tr. at Vol. 10, p. 43. Dr. Scott's name appears on various patents pertaining to these devices. Along with several other principals, Dr. Scott founded American Medical Systems ["AMS"] to manufacture and market some of these devices. Tr. at Vol. 10, p. 103.

Both Lozier and Dr. Scott agreed that Lozier came to Houston to obtain an implant of the urethral sphincter, in order to control the flow of his urine. Tr. at Vol. 16, p. 51 (Lozier), and Vol. 10, p. 108 (Dr. Scott). Lozier wanted the sphincter implant, and signed a **written informed consent** for the sphincter surgery. Dr. Scott successfully implanted the sphincter into Mr. Lozier's abdomen; Mr. Lozier has had no significant problems

resulting from the sphincter; and the sphincter is not at issue in this litigation.

Unfortunately, as Nick Lozier -- under general anesthesia -- was being wheeled into the operating room to receive the sphincter, the charge nurse pointed out to Dr. Scott that he had scheduled Mr. Lozier not only for the implantation of the sphincter, for which Mr. Lozier had signed a written consent form, but also for the implantation of a penile prosthesis, for which he had signed no such form.[1] Tr. at Vol. 10, p. 10 (Dr. Scott). Nonetheless, Dr. Scott made a unilateral, conscious decision to proceed with **both** surgeries, even though there was no written consent form for the penile implant. Tr. at Vol. 10, p. 10, 15 (Dr. Scott). There is no question that Dr. Scott was fully aware that Mr. Lozier had not signed

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[1] Mr. Lozier had discussed the possibility of a penile prosthesis with Dr. Scott, but had decided against it.

a written, informed consent for the implantation of the penile prosthesis prior to and during the surgery.

Furthermore, Dr. Scott proceeded with the penile implant with full knowledge that federal statutes and regulations **required** a written consent form signed by the patient for this type of device. The penile prosthesis at issue is called a Hydroflex. Before Nick Lozier's operation, Dr. Scott's company, AMS, had secured an Investigative Device Exemption from the Federal Food and Drug Administration ["FDA"] pursuant to 21 U.S.C. §360j(g) to implant the Hydroflex in 100 patients on an experimental basis. One of the purposes of the clinical trials was to determine the degree to which the Hydroflex could maintain rigidity in a man with a large penis. Px 53. Dr. Scott found the perfect subject for this aspect of the clinical trials in Nick Lozier, whom Dr. Scott has described as in a "class by himself." Tr. at Vol. 10, p. 58.

As the inventor of the Hydroflex device, a founder and officer of AMS, and the chief physician involved in the clinical experiments, Dr. Scott participated actively in AMS' request for FDA approval and even signed a written document promising the federal regulators that he would make sure that his patients gave their consent in the form and manner required by federal law. Px 2.

Furthermore, the surgical protocol for the Hydroflex device at St. Luke's Hospital, where Dr. Scott practiced, and elsewhere, required a detailed, written form. Tr. at Vol. 10, p. 29, 39-42 (Dr. Scott). Indeed, Dr. Scott **wrote** (or revised) the Informed Consent document to be used in the clinical trials. Px 7 is his letter with a copy of his revisions to the Informed Consent. Thus, Dr. Scott established a standard of disclosure for the "Hydroflex" clinical trials requiring written disclosure, but then failed to adhere to his own standard.

Despite the fact that Dr. Scott had invented the Hydroflex; despite the fact that he knew that it was an experimental device which he could use only because the FDA had granted an exception to its usual regulatory requirements, and which could not be licensed for commercial use until its clinical probation had ended; despite the fact that he was familiar with the written consent requirement of the federal statute and regulations concerning the implantation of this device in human subjects; despite the fact that he had helped write the Informed Consent form that was to be signed by the subjects in the clinical experiment phase; despite the fact that he had expressly promised the federal regulators that he would insure that he obtained written, informed consent as required by law before implanting the Hydroflex into any participant in the experiments; despite the fact that he had found in Nick Lozier a one-of-a-kind

subject, and that he had a direct financial incentive to pass quickly through the clinical trials so that he could reap the benefits of commercial licensing of the Hydroflex[2], both of which called his objectivity directly into question; and despite the fact that he knew that Nick Lozier had NOT signed the required Informed Consent form to participate in the experiment, Dr. Scott proceeded with his irreversible experiment, and implanted the Hydroflex in Nick Lozier's penis on January 24, 1984.

The penile implant was a disaster. It was extremely painful for Lozier. Tr. at Vol. 16, p. 54. It never worked properly. Tr. at Vol. 17, p. 67. Ultimately, Mr. Lozier

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[2] Although the District Court instructed the jury that "[t]he law, however, does not require that consent to surgery be in writing," essentially reducing the consent issue to a swearing match between a world-famous physician and a "country-boy type" with a ninth-grade education, the Court did not allow the jury to consider Dr. Scott's direct financial incentive to implant as many Hydroflexes as possible in assessing his credibility. After the Hydroflex clinical trials were completed, Dr. Scott sold his stock in AMS for over $5,000,000.00. Tr. at Vol 10, p. 177.

had to have it removed. Tr. at Vol. 16, p. 58. In all likelihood, the implantation of the Hydroflex device by Dr. Scott caused **irrevocable**, irreversible tissue damage, so that Lozier is now permanently, organically, impotent. See Tr. at Vol. 17, p. 91 (Mr. Lozier), Vol. 20, p. 35 (Mrs. Lozier).[3]

In his own defense, Dr. Scott testified that he had spoken to Mr. Lozier before the operation, and that Mr. Lozier had informed Dr. Scott that he wanted both the urethral sphincter and the penile implant. Tr. at Vol. 10, p. 12. Lozier maintained steadfastly that he did **not**

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[3] There was considerable dispute in the record concerning the degree to which Nick Lozier was impotent prior to the surgery by Dr. Scott. Both Loziers maintained that, although Nick did not maintain as full an erection as he had previously enjoyed, he was still able to consummate sexual intercourse to the mutual satisfaction of himself and his wife. Tr. at Vol. 17, p. 83; Vol. 20, p. 27. According to the definition of impotency used by all of the experts in this case, this meant that Lozier was **not** impotent, and, therefore, not even a candidate for the Hydroflex prosthesis. Tr. at Vol. 19, p. 75, 124 (Dr. Hopkins); Vol. 12, p. 455 (Dr. Scott); Vol. 7, p. 3 (Dr. Paulsen).

consent to implantation of the penile prosthesis, because he was not convinced that he needed it or wanted it. Tr. at Vol. 16, p. 48. Although the jury -- without the benefit of the federal regulations, tendered as Px 63, and the evidence of Dr. Scott's direct financial bias in implanting as many Hydroflexes as quickly as possible, but **with** the District Judge's instruction that consent could be oral -- did not find that Dr. Scott implanted the Hydroflex without Lozier's consent, the Loziers assert that the jury should have never even considered this issue. As a matter of law, 21 U.S.C §360j(g), and the regulations promulgated thereunder, Protection of Human Subjects, 21 C.F.R. §50.1, et seq., superseded the issue of consent to the use of experimental devices on human subjects. The Fifth Circuit erred in holding to the contrary.

ARGUMENT AND AUTHORITIES

A. Framing the Issue

Much as an antitrust litigant must first determine the relevant product and market, the first task in the case at bar is to determine the scope of the Loziers' assertions. Dr. Scott has successfully advanced the idea in the Courts below that:

> the issue in this case is whether Congress intended, by passage of the Federal Food, Drug and Cosmetic Act (FDCA), to compel the states to provide for civil tort recovery for any failure to document consent in writing.

Brief of Appellant F. Brantley Scott, Jr., M.D. in the United States Court of Appeals for the Fifth Circuit at 12. The Fifth Circuit adopted Dr. Scott's approach. Opinion at 5.

The Loziers have not made such a sweeping assertion in this case. First and foremost, the holding in this case does not apply to all medical negligence cases involving the issue of informed consent. The Hydroflex was a "device for investigational use" -- an experimental

device on probation until it had proven its worth and reliability in controlled, clinical tests. 21 U.S.C. §360j(g). Certainly, the analysis of how a subject must consent to the use of an experimental device on probation is vastly different than the analysis of how a patient may consent to the use of a proven device or a routine procedure in commercial use.

Second, the Loziers do not contend that the FDCA compels (or, for that matter, could compel) the State of Texas to enact a comprehensive scheme for civil tort recovery. Dr. Scott attempts to argue that, if a federal statute preempts state law, it must do so on a grand scale. This is not true. If a federal statute preempts state law, it need not preempt every facet of the preempted subject.

As any first-year law student could attest, a tort consists of a duty, breach of that duty, causation and damages. The Loziers do not argue that 21 U.S.C.

§360j(g) and 21 C.F.R. §50.1 et seq. establish the tort of negligence based on failure to obtain informed consent under Texas law, or define its elements. What 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 do in this regard is **define the duty -- how one must obtain informed consent -- in the limited area of "Investigational Devices."** Likewise, concerning the Lozier's theory that Dr. Scott committed battery by implanting a Hydroflex in Nick Lozier's penis, the federal statute and regulations do not create the tort of battery in Texas, or alter the elements of or defenses to that tort. The federal statute and regulations do, however, define how one must consent to what would otherwise constitute a battery, where the tortfeasor commits the battery by implanting an "Investigational Device."

The Loziers and Dr. Scott have drawn the battle lines clearly. The Loziers assert that, when dealing with

"Investigational Devices," informed consent must be in writing, period. Dr. Scott asserts that the subject may give his informed consent orally.

B. **The Statutory Framework**

Congress amended the Food, Drug and Cosmetic Act ["FDCA"] in 1976 to confer authority on the FDA to regulate both drugs and medical devices. P.L. 94-295, 90 Stat. 574 (May 28, 1976)(codified at 21 U.S.C. §§301-92). Section 360j of the FDCA sets forth "[g]eneral provisions respecting control of devices intended for human use," and prescribes regulations applicable to such devices.

The statutory section at issue in this lawsuit, 21 U.S.C. §360j(g), provides an "[e]xemption for devices for investigational use," and exempts "investigational devices" from the usual regulatory requirements of the FDCA. In their stead, section 360j(g) prescribes its own regulatory requirements for "investigational devices" that are separate

from and more stringent than the requirements applicable to other devices regulated by the FDCA, based on the unproven nature of such devices.

> It is the purpose of [21 U.S.C. §360j(g)] to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

21 U.S.C. §360j(g)(1). Accordingly, Congress enacted section 360j(g) to encourage invention and innovation, but only to the extent consistent with public health and safety and with ethical standards.

The most important provision of 21 U.S.C. §360j(g) with regard to public health and safety and to ethical standards addresses the issue of informed consent. If citizens are to participate in experiments, the scientist must fully inform them as to the risks, and must obtain

their knowing consent. Congress mandated that the person applying for an investigative device exemption

> (D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except [in life-threatening situations] . . .
>
> The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

21 U.S.C. §360j(g)(3).

The Regulations promulgated under 21 U.S.C. §360j(g) are set forth at 21 C.F.R. §50.1, et seq., under the general heading "PROTECTION OF HUMAN SUBJECTS." Subpart B -- Informed Consent of Human Subjects addresses the issue of informed consent, and specifically mandates that

> [e]xcept as provided in §56.109(c), informed consent **shall** be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.

21 C.F.R. §50.27(a)[emphasis added].

There is no dispute that the Hydroflex penile prosthesis that Dr. Scott implanted in Nick Lozier on January 24, 1984 was an "Investigative Device" subject to the requirements of 21 U.S.C. §360j(g) and the Regulations promulgated thereunder. Likewise, there is no dispute that Nick Lozier never signed a written Informed Consent for the implantation of the Hydroflex.

Finally, the Loziers cite portions of the FDCA and the Regulations that provide some guidance on whether Congress intended to preempt state law regarding informed consent concerning investigative devices.

> **(a) General rule**. Except as provided in subsection (b), no State or political subdivision of a State may establish or

continue in effect with respect to a device intended for human use any requirement --

> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) Exempt requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if --

> (1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; . . .

21 U.S.C. §360k[underlining added; boldface in original].

The regulations provide that:

> (c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require **additional** information to be disclosed for informed consent to be legally effective.

21 C.F.R. §50.25[emphasis added].

The clear message from these provisions is that Congress intended the federal statute and regulations to establish the minimum standard for informed consent concerning "investigational devices." If a State wishes to impose additional, more stringent requirements for informed consent to be legally binding, it can do so. However, a State cannot allow a human subject involved in research to consent to the use of an investigative device in any manner that does not meet the federally-imposed minimum standard. The Loziers assert that, under the Statute and Regulations, Nick Lozier could not legally

consent to the implantation of the Hydroflex except in writing.[4]

C. **A Subject Cannot Consent to the Use of an Investigative Device Governed by 21 U.S.C. §360j(g) Except in Writing**

The Loziers assert that 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 set the minimum standard that any purported consent to the use of an "investigational device" must meet. To the extent that this minimum standard

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[4] Interestingly, Texas law also indicates that consent should be given in writing:

> **Manner of Disclosure**
>
> Section 6.06. Consent to medical care that appears on the panel's list requiring disclosure shall be considered effective under this subchapter if it is given in writing, signed by the patient or a person authorized to give the consent and by a competent witness, and if the written consent specifically states the risks and hazards that are involved in the medical care or surgical procedure in the form and to the degree required by the panel under Section 6.04 of this subchapter.

Tex.Rev.Civ.Stat.Ann. art. 4590i (Vernon Supp. 1991). Thus, the District Judge's instruction that "[t]he law, however, does not require that consent to surgery be in writing" appears all the more curious.

conflicts with state law, the federal statute and regulations would preempt any form of consent that falls below this standard (i.e. that is not in writing). In the case at bar, however, there is not necessarily a conflict. The District Judge simply assumed that consent under Texas common law, developed to analyze informed consent in the context of routine devices and procedures, was the same as consent to participation in research involving "investigational devices" as understood by 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27. In so doing, the District Judge equated apples and oranges -- or, more appropriately, apples and kumquats. This was entirely inappropriate. While oral consent may be perfectly acceptable in routine devices and procedures, it is certainly not acceptable when dealing with devices to which 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 apply. The Loziers assert that, as a matter of law, the

federal statutes apply to consent to participate in research involving investigational devices, and state law applies to consent to routine matters. Accordingly, the District Court erred in refusing to apply the federal statute and regulations to the case at bar.

In the alternative, if the federal statute and regulations do conflict with state law regarding consent, the federal statute and regulations preempt state law with regard to investigational devices. To determine whether there is federal preemption of any particular subject, one must ascertain whether Congress intended to preempt state law on that subject.

There are three principal indications of preemption. First, Congress can expressly state that it intends to preempt state law. This method is sufficient, though not necessary, to demonstrate federal preemption. **International Paper Co. v. Ouellette**, 107 S.Ct. 805, 811

(1987). Second, courts may infer preemption "when the federal legislation is 'sufficiently comprehensive to make reasonable the inference that Congress "left no room" for supplementary state regulation.'" **Ibid.**(ultimately quoting **Rice v. Santa Fe Elevator Corp.**, 331 U.S. 218, 230 (1947)). Finally,

> [i]n addition to express or implied pre-emption, a state law also is invalid to the extent that it "actually conflicts with a . . . federal statute." **Ray v. Atlantic Richfield Co.**, 435 U.S. 151, 158, 98 S.Ct. 988, 994, 55 L.Ed.2d 179 (1978). Such a conflict will be found when the state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" **Hillsborough County v. Automated Medical Laboratories, supra**, 471 U.S., at 713, 105 S.Ct., at ___ (quoting **Hines v. Davidowitz**, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed.2d 581 (1941).

Ouellette, 107 S.Ct., at 811. Under either the second or third types of preemption, 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 supersede Texas state law to the extent that Texas law would permit a human subject to

consent orally to the use of an "investigational device" such as the Hydroflex.

Preemption is most obvious under the third, "conflict with state law" analysis. If Dr. Scott (and the District Court) is correct in his assertion that Nick Lozier could consent orally to the implantation of the Hydroflex -- at least as a defense to battery -- there is a blatant conflict with 21 C.F.R. §50.27(a), which mandates that consent be documented on an approved, written consent form.

Texas law allows a medical negligence plaintiff in Nick Lozier's position to recover under a theory of battery. The lead case in Texas unambiguously states the rule of law as follows:

> [A] surgeon is subject to liability for assault and battery where he operates without the consent of the patient or the person legally authorized to give such consent.

Gravis v. Physicians & Surgeons Hospital, 427 S.W.2d 310, 311 (Tex. 1968). Accord **Johnson v. Whitehurst**, 652 S.W.2d 441, 444 (Tex. App. -- Houston [1st Dist.] 1983, writ ref'd n.r.e.)("a doctor must secure the authority or consent of his patient in order to legally perform medical procedures."). Consent is an affirmative defense to battery. Likewise, it is clear that the purpose of 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20 - 50.27 is to protect human subjects from participation in experiments involving "investigational devices" until the scientist explains all the risks involved and allows the subject to see them in writing, reflect on them and physically consent to them by his/her signature. Did Congress intend Dr. Scott's proferred result: that oral consent to the implantation of an experimental device is adequate as a defense to battery, thereby depriving a plaintiff such as Nick Lozier of exactly the protection that Congress has afforded him?

Certainly not. Such a result would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." **Ouellette**, 107 S.Ct., at 811.

This analysis is a fortiori true of the Loziers' negligence/lack of informed consent theory. Again, if oral consent could suffice, Dr. Scott would negate Congress' protection for human subjects like Nick Lozier in its entirety, rendering the express words of 21 U.S.C. §360j(g) and 21 C.F.R. §50.27(a) utterly meaningless.

In summary, the method that Congress chose to reach its goal of protecting public health and safety and upholding ethical standards in the area of "investigational devices" was to require a written consent form documenting informed consent. To allow oral consent where an "investigational device" is involved would frustrate Congress' intent. "A state law [] is preempted if it interferes with the methods by which the federal statute

was designed to reach [Congress'] goal." **Ouellette**, 107 S.Ct., at 813.

The Court could reach the same result using the "implied preemption" analysis. At first blush, it appears that 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20 - 50.27 are not "sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." **Ouellette**, 107 S.Ct., at 811. This seems particularly true in light of the following language:

> The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

21 C.F.R. §50.25(c). See also 21 U.S.C. §360k(b). However, the analysis must return to the intent of Congress: to establish the minimum standard for informed consent to the use of "investigational devices." In fact, Congress left no room for supplementary state regulation

of anything less than the federal standards for informed consent. See **Ouellette**, 107 S.Ct., at 810, 812 (Clean Water Act, 33 U.S.C. §1251 et seq., provision that allowed state in which a pollution source was located to adopt more stringent discharge limitations than those of the federal government was valid to preempt attempted application of the laws of adjacent states).

As the Loziers pointed out above, Dr. Scott has implied that a federal statute must set forth a comprehensive civil tort recovery scheme in order to preempt state law that overlaps the federal statute. This is simply untrue. Federal law can preempt certain provisions of state law, while leaving other provisions in force. See **Ouellette**, 107 S.Ct., at 814-15 (Vermont residents allowed to maintain nuisance action in federal court, sitting in Vermont, against company with pollution point source discharge in New York, despite provisions of

Clean Water Act; BUT Clean Water Act mandated that court apply substantive law of New York). Just as the plaintiffs in **Ouellette** were able to maintain their action in Vermont, with federal law supplying only the choice of law, the Loziers may maintain their action against Dr. Scott under Texas law, with federal law supplying only the standard for consent.

D. **Using a Federal Statute to Supply the Duty or the Defense for a State Tort Remedy is Entirely Consistent with Both Texas and Federal Law**

This Court has recognized that there can be circumstances where "'a breach of the duty imposed by the federal statute'", gives rise to state tort claims. **Merrell Dow Pharmaceutical, Inc. v. Thompson**, 478 U.S. 804, 106 S.Ct. 3229, 3236n.14 (1986)(quoting **Moore v. Chesapeake**

& Ohio R. Co., 291 U.S. at 214-15).[5] That is precisely the issue in this case.

This holding is entirely consistent with Texas law. Texas courts have long recognized that the breach of a statute, ordinance, or regulation is negligence per se so long as it is clear to the court that the plaintiff is a member of the class of persons for whom the law in question is designed to protect. **El Chico Corp. v. Poole,** 732 S.W.2d 306, 312 (Tex. 1987)(establishing per se liability for violation of alcoholic beverage code); **Nixon v. Mr. Property Mgt. Co.,** 690 S.W.2d 546, 549 (Tex. 1985). The Texas Court of Appeals in San Antonio has made it quite clear that the statute or regulation which establishes the duty can be **federal.** **Peek v. Oshman's Sporting Goods, Inc.,** 768 S.W.2d 841, 845 (Tex.App. -- San

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[5] At a minimum, Dr. Scott's violation of 21 U.S.C. §360j(g) should "constitute a 'rebuttable presumption' or a 'proximate cause' under state law." **Merrell Dow**, 478 U.S. at 812, 106 S.Ct. at 3234.

Antonio, 1989, writ denied)(affirming summary judgment for defendant because no fact issue raised violation of federal firearms statute and implementing regulations, but specifically acknowledging that "we here recognize a standard of care imposed by statute").

CONCLUSION

For the reasons set forth above, Petitioners urge the Court to hold that, while oral consent to routine medical devices and procedures under state law may be acceptable, written consent pursuant to 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 is required for a human subject to participate in research involving "investigational devices."

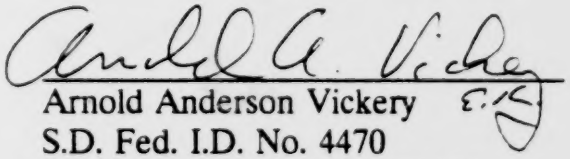
In the alternative, if the Court finds that there is a conflict between 21 U.S.C. §360j(g) and 21 C.F.R. §§50.20-50.27 on the one hand, and state law permitting oral consent on the other, Petitioners urge the Court to

hold that the federal statute and regulations preempt state law concerning the method of giving consent to one's participation in experiments involving "investigational devices," as a matter of law.

In the alternative, Petitioners urge the Court to hold that the District Court could and should have at least admitted the regulations into evidence and given the jury appropriate instructions concerning the mandatory nature of these laws, and to remand the case on that basis.

Respectfully submitted

VICKERY, KILBRIDE, GILMORE
& VICKERY



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PROOF OF SERVICE
CERTIFICATE OF SERVICE

Pursuant to Rule 29.3 of the Rules of the Supreme Court of the United States, I certify that three copies of the Petition for Writ of Certiorari has been served on Robert J. Swift, FULBRIGHT & JAWORSKI, 1301 McKinney, Suite 5100, Houston, Texas 77010-3095 via first class postage prepaid, on this 13th day of November, 1991.